REMARKS

Claims 35-47 are pending. Claims 1-34 were previously cancelled without prejudice. No new matter has been added.

Rejections under 35 U.S.C. § 102(e)

Claims 35-47 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,264,650 to Hovda et al. ("Hovda"). Applicants traverse these rejections.

Hovda describes a device for electrosurgical treatment of an intervertebral disc. The device has a plurality of electrodes capable of applying electrical energy to a target location to ablate or stiffen tissue. In some embodiments, "[t]he current flow path between the electrode terminals and the return electrode(s) may be generated by submerging the tissue site in an electrical conductive fluid...or by directing an electrically conducting fluid along a fluid path to the target site (i.e., a liquid, such as isotonic saline, hypotonic saline or a gas, such as argon)." (Hovda at 15:62-16:1). Other conductive fluids, such as "blood or intracellular saline" are also described. (*Id.* at 16:10-12).

Claims 35 and 47 recite "at least one therapeutic substance delivery effector...capable of delivering a therapeutic substance." Applicants previously submitted that Hovda does not disclose an effector for delivering of a *therapeutic substance*, and therefore does not anticipate claims 35-47. (*See* Amendment under 37 C.F.R. § 1.111 dated December 5, 2005 at 5). In response, the Examiner cited the article "Use of Epidural Steroids in the Treatment of Sciatica," AMERICAN FAMILY PHYSICIAN, Vol. 56, No. 8, (1997) ("American Family Physician article") for the proposition that "[i]t is common knowledge that isotonic saline has been used to [*sic*] human conditions such as lumbar disc problems." (Final Rejection mailed February 17, 2006 at 2-3).

Applicants respectfully submit that the American Family Physician article does not support the notion that isotonic saline is a "therapeutic substance." The American Family Physician article describes a randomized, *double-blind* trial to treat patients with sciatica with either methylprednisolone or isotonic saline. The article notes that after three weeks, "no significant difference was apparent between the patients receiving methylprednisolone and those receiving *placebo* in clinical and functional outcomes." (*Id.* at 2098) (emphasis added). Thus, it is clear in this study that istonic saline was used as a placebo, which necessarily is absent therapeutic effect. This is exactly the point of a randomized double-blind study — to randomly provide some patients with a drug (in this case, methylprednisolone), and others with a non-therapeutic placebo (in this case, isotonic

saline) — to neutralize any psychosomatic effects that may manifest simply from knowingly being administered a substance.

Applicants also respectfully submit that publications describing the use of isotonic saline as a placebo are legion. For example, isotonic saline has been used as a placebo in tension headache treatment trials (*see* U.S. Patent No. 5,376,672 to Pilgrim at 4:48-55, attached in Appendix A), and has also been expressly recognized and used as a placebo in conducting epidural injection trials for the treatment of sciatica (*see* "Epidural Injections: No Significant Functional Benefit for Sciatica," DYNAMIC CHIROPRACTIC, Vol. 15, Issue 21 (1997), attached in Appendix B), which is the same subject matter as the American Family Physician article cited by the Examiner.

Accordingly, since the American Family Physician article does not support the Examiner's claim that isotonic saline is a therapeutic substance, and Hovda does not disclose an effector for delivering of a therapeutic substance, Hovda fails to describe each and every element of independent claims 35 and 47. The rejections of independent claims 35 and 47, along with the rejections dependent claims 36-46, should therefore be withdrawn.

Statement of the Substance of the Interview

The Examiner and the undersigned conducted an Interview on April 4, 2006 regarding the instant application. The undersigned stated that Applicants believed that the American Family Physician article failed to describe isotonic saline as a therapeutic substance, pointing out the passages describe above. The Examiner disagreed.

CONCLUSION

It is believed that claims 35-47 are in condition for allowance.

No fee is believed due for this response. If any fee(s) are due at this time, please charge such fee(s) to Jones Day Deposit Account No. 503013.

Respectfully submitted,

Date: May 12, 2006

54,390

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APPENDIX A

U.S. Patent No. 5,376,672 to Pilgrim